IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Bryan Windus-Smith et al.

Serial No.: Unassigned Art Unit: Unknown

Filed : Herewith Examiner: Unknown

For : MEDICAL DEVICE PACKAGE, KIT AND ASSOCIATED METHODS

EXPRESS MAIL LABEL NO.: EL 373 756 955 US

Mail Stop: Patent Application Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §\$1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☐ In accordance with §1.97(b), since this Information
Disclosure Statement is being filed either within three months
of the filing date of the above-identified national application

(other than a continued prosecution application under \$1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in \$1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under \$1.114, no additional fee is required.

•
In accordance with §1.129(a), this Information
Disclosure Statement is being filed in connection with 🗌 the
first or _second After Final Submission, therefore:
<pre>Statement in Accordance with §1.97(e)</pre>
(attached); or
☐ Please charge Deposit Account No. 10-
0750/ / the fee of $$180.00$ as set forth
in §1.17(p).
In accordance with §1.97(c), this Information
Disclosure Statement is being filed after the period set forth
in \$1.97(b) above but before the mailing date of either a Final
Action under §1.113 or a Notice of Allowance under §1.311, or
an action that otherwise closes prosecution and that it is
accompanied by one of:
Statement in Accordance with §1.97(e)
(attached); or
Please charge Deposit Account No. 10-
0750/ / the fee of \$180.00 as set forth
in $\$1.17(p)$.
55 5 5 7 (P)
In accordance with §1.97(d), this Information
Disclosure Statement is being filed after the mailing date of
either a Final Action under §1.113 or a Notice of Allowance
under §1.311 but before the payment of the Issue Fee.
Applicant(s) hereby petition(s) for consideration of this

Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in \$1.17(p). Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith. Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT: П In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith. П If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request. \boxtimes Copies of only foreign patent documents and nonpatent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i). 冈 There are no listed references which are not in the English language. \Box The relevance of those listed references which are not in the English language is as follows:

Information Disclosure Statement. Included are: Statement in

attached Submission Under MPI	tion(s), which are listed on the EP 609 D.
Attached are the f	ollowing non-published pending
patent applications which may	y be deemed relevant, which are
listed on the attached Submis	ssion Under MPEP 609 D.
Please charge any defic	iency or credit any overpayment to
Deposit Account No. 10-0750/	DDI-5016/MM.
	Respectfully submitted,
	Mayumi Maeda
	Reg. No. 40,075 Attorney for Applicants
Tahmaan 6 Tahmaan	
One Johnson & Johnson Plaza	
Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (408) 956-4790 DATED: 9/19/33	

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)
Sheet 1 of 1

Application Number	Unassigned		
Filing Date	Herewith		
First Named Inventor	Windus-Smith et al.		
Group Art Unit	Unknown		
Examiner Name	Unknown		
Attorney Docket Number	DDI-5016		

				U.S. PATENT DOCUMENTS		
_		U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
Examiner Initials	Cite No.1	Kind Code ² Number (if known)				
		5,035,703		Baskas	07/30/1991	
		6,176,119	B1	Kintzig	01/23/2001	
		6,497,845	B1	Sacherer	12/24/2002	
		2003/0036200	A1	Charlton	02/20/2003	
_						
		•				

FOREIGN PATENT DOCUMENTS Foreign Patent Document Date of Publication Pages, Columns, Lines, of Cited Document where relevant Name of Patentee or Examiner Cite passages or relevant Т⁶ mm-dd-yyyy Applicant of Cited Document figures appear Initials KindCode⁶ Number⁴ No.1 Office⁵ 1 118 856 Omron Corp. 07/25/2001 A1 ΕP 1 285 695 A2 02/26/2003 wo 01/64105 A1 Inverness Medical Technology, Inc. 09/07/2001 wo 02/49507 Α1 Inverness Medical Ltd. 06/27/2002 A2 02/27/2003 WΩ 03/015627 Inverness Medical Ltd.

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

¹ Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.